

OraSure Testing Protocol

It is assumed the agency employing the counselor (whose documented training was from a NYSDOH certified training program) currently has on hand:

- a medical record system or other suitable record keeping system in which each individual's information can be stored and retrieved
- a policy and procedure for providing confidential HIV Counseling & Testing in accordance with NYS law and NYSDOH guidelines
- a tracking system for handling specimens and results
- an agreement and current account with a NYSDOH approved lab to process the results
- a qualified and legally authorized employee who can order HIV testing (such as a physician), who will verify the results, and be responsible for the reporting of the HIV positive results to the person, as well as to the mandated city, county or state health department.

For each person who agrees to be tested, you will need one test packet containing the necessary documents and forms (**underlined below**) and an OraSure test kit. A test kit includes a device and processing conducted by LabOne.

1. Register the person using your Agency's Intake or Registration Form.

2. Begin counseling using your agency's Pre-test Counseling Form or progress note.
3. If the person appears psychologically ready for testing, proceed with obtaining informed consent and with testing.
4. Have the person sign the NYSDOH HIV Consent Form and print their name beside their signature; if an anonymous test, the client would print the assigned code number.
5. Counselor must also sign Consent Form, print name and facility on the form.
6. Open the OraSure Packet from LabOne that includes:
 - Patient Information Pamphlet
 - OraSure Instructions
 - OraSure spatula and vial
 - OraSure Lab Requisition Form
7. Place 1st label from the OraSure Lab Requisition Form on vial.
8. Place 2nd label on Consent Form near patient signature.
9. Write the ID number from the label on your agency's Pre-Test Counseling form.
10. Complete the OraSure Lab Requisition Form.

A unique ID number may be assigned to track specimens: ID # consists of the first two letters of your testing program + patient birth date + person's initials. (for example, if your program is FA (Fictitious Agency),

01/03/62 is the patient date of birth (Jan. 3, 1962), JD are the person's initials (John Doe), then the ID# = FA010362JD) If a Counseling and Testing Scannable (CTS) data form is used, a 10-digit identification code will be assigned to each form.

11. Follow "How-To" Instruction sheet in the packet to perform the oral test. Place the swab in container, break off tip of swab, and close container (listen for click when closing).
12. Keep the physician copy of the OraSure Lab Requisition Form and attach it to Consent Form.
13. Place specimen in box with Lab Requisition Form and send express mail.
14. Complete your agency's Encounter Form or Project WAVE CTS form.
15. Complete your agency's offsite HIV Pre/Post-test Follow-up Record Form or other appropriate log that includes the person's name, medical record# (if available or other unique record number), person's OraSure lab specimen ID number, and Lab Requisition Form bar code number, pre-test date and post-test appointment dates.
16. The physician copy of the OraSure Lab Requisition Form, the Consent Form, the Pre-test Counseling Form, the Intake/Registration Form, and a completed Encounter Form are kept together in a folder and can be used to create a medical record or other record for your agency's system.
17. Persons tested must be given an appointment for Post-test Counseling within 2 weeks (make it clear

whether they can meet you back at the Project WAVE site or another site).

18. The OraSure test results can be sent by confidential fax to your agency's authorized employee who ordered the test or their designee. The original result must be kept in the medical record or other suitable confidential file and a copy should be sent to the Pre-test Counselor listed on the Consent Form before the Post-Test counseling appointment.
19. OraSure results must be reported if positive to the person and the mandated city, county or state health department. (Complete the Medical Provider HIV/AIDS and Partner/Contact Report Form DOH-4189).
20. If person requests a copy of their test result, they must sign a New York State "Authorization for Release of Confidential HIV Related Information" Form. This form is then placed in the medical record or other individual file your agency is using.
21. Report demographic data with no individual names or identifiers (using the CTS form developed for Project Wave NY events) to the AIDS Institute for Project WAVE at end of the Pre-test day; two weeks after pre-test all results should be reported. After that, report weekly on the number of additional post-test counseling sessions completed.